

## Appendix A

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Claim Amendments

1. (Currently amended) A pharmaceutical formulation comprising a pharmaceutical acceptable salt of glycopyrronium, a solvate ~~solvates~~ or physiologically functional derivative thereof in combination with ciclesonide, a pharmaceutically acceptable salt, solvate ~~solvates~~ or physiologically functional derivative thereof and a pharmaceutically acceptable carrier and/or one or more excipients, ~~and optionally one or more other therapeutic ingredients.~~
2. (Currently amended) ~~Formulation~~ The formulation according to claim 1, wherein the pharmaceutical acceptable salt of glycopyrronium and ciclesonide are contained in the same pharmaceutical formulation (fixed combination).
3. (Currently amended) ~~Formulation~~ The formulation according to claim 1, wherein the pharmaceutical acceptable salt of glycopyrronium and ciclesonide are

contained in different pharmaceutical formulations (free combination).

4. (Currently amended) ~~Formulation~~ The formulation according to claim 1, comprising a compound selected from the group consisting of [11 $\beta$ ,16 $\alpha$ (R)]-  
-16,17-[ (Cyclohexylmethylen)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)pregna-1,4-dien-3,20-dion, [11 $\beta$ ,16 $\alpha$ (S)]-  
-16,17-[ (Cyclohexylmethylen)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxoprop-oxy)pregna-1,4-dien3,20-dion, [11 $\beta$ ,16 $\alpha$ (R,S)]-16,17-[ (Cyclohexyl-methylen)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxoprop-oxy)pregna-1,4-dien3,20-dion, 16 $\alpha$ ,17-(22R)-Cyclohexylmethylenedioxy-11 $\beta$ ,21-dihydroxy-pregna-1,4-dien-3,20-dion, 16 $\alpha$ ,17-(22S)-Cyclohexylmethylenedioxy-11 $\beta$ ,21-dihydroxy-pregna-1,4-dien-3,20-dion and 16 $\alpha$ ,17-(22R,S)-Cyclohexylmethylenedioxy-11 $\beta$ ,21-dihydroxy-pregna-1,4-dien-3,20-dion.

5. (Currently amended) ~~Formulation~~ The formulation according to claim 1, wherein the pharmaceutical acceptable salt of glycopyrronium is selected from [[form]] the group consisting of ~~compounds~~ racemic forms [S,S-, S,R, R,S- and R,R-forms] of the pharmaceutical acceptable salt of glycopyrronium in any mixing ratio and enantiomerically enriched S,S-, S,R, R,S- and R,R-forms of the pharmaceutical acceptable salt of glycopyrronium.

6. (Currently amended) ~~Formulation~~ The formulation according to claim 5, wherein the enantiomerically enriched form of the pharmaceutical acceptable salt of glycopyrronium is the R,R-form (i.e. (3R,2'R)-3-[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidinium).

7. (Currently amended) ~~Formulation~~ The formulation according to claim 6, wherein the R,R-form has an enantiomeric purity of 90% minimum enantiomeric excess (ee), ~~preferably 95 % ee, more preferably more than 98 % ee, and in particular preferably more than 99.5 % ee.~~

8. (Currently amended) ~~Formulation~~ The formulation according to claim 1, wherein the pharmaceutical acceptable salt of glycopyrronium is (3R,2'R)-3-[ (cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidinium bromide, which substantially does not contain glycopyrronium in the S,S-, S,R- and/or R,S- forms.

9. (Currently amended) ~~Formulation~~ The formulation according to claim 1, comprising pharmaceutical acceptable salt of glycopyrronium and ciclesonide in an amount and ratio to be effective for a twice or once daily treatment of a clinical condition in a mammal, ~~such as a human~~, for which a corticosteroid and/or an anticholinergic agent is indicated.

10. (Currently amended) ~~Formulation~~ The formulation according to claim 1, which is suitable for administration by inhalation.

11. (Currently amended) ~~Formulation~~ The formulation according to claim 1, which is suitable for nasal administration.

12. (Currently amended) ~~Pharmaceutical~~ The formulation according to claim 1, which is a dry powder and the carrier is a saccharide.

13. (Currently amended) ~~Pharmaceutical~~ The formulation according to claim 12, wherein the carrier is lactose monohydrate.

14. (Currently amended) ~~Method for the prophylaxis or A~~ method of treatment of a clinical condition in a mammal, ~~such as a human,~~ for which a corticosteroid and/or an anticholinergic agent is indicated, which comprises administration of a therapeutically effective amount of a pharmaceutical formulation comprising ciclesonide or a pharmaceutical acceptable salt, solvate, or physiologically functional derivative thereof in combination with a pharmaceutical acceptable salt of glycopyrronium, a solvate, or physiologically functional derivative

thereof, and a pharmaceutical acceptable carrier and/or one or more excipients.

15. (Currently amended) ~~Method~~ The method according to claim 14, wherein the clinical condition is selected from the group consisting of asthma, nocturnal asthma, exercise-induced asthma, chronic obstructive pulmonary diseases (COPD), chronic bronchitis, [[and]] wheezy bronchitis, emphysema, [[,]] shortness of breath, respiratory tract infection, [[and]] upper respiratory tract disease, rhinitis, allergic rhinitis and seasonal rhinitis.

16. (Currently amended) ~~Method~~ The method according to claim 15, which comprises a twice daily dosage regimen.

17. (Currently amended) ~~Method~~ The method according to claim 15, which comprises a once daily dosage regimen.

18. (Currently amended) ~~Method~~ The method according to claim 15, which comprises administration of a combination of [[the]] a pharmaceutical acceptable

salt of glycopyrronium and ciclesonide in the same administration form by inhalation from an inhaler and wherein each actuation provides a dose therapeutically effective for a twice daily dosing regimen or for a once daily dosing regimen.

19. (Currently amended) ~~Dry~~ A dry powder inhalation product comprising a pharmaceutical composition according to claim 13.